



IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

Serial No.: 10/679,714)
Applicant: A. Awad)
Filed: October 6, 2003)
Title: REDUCTION OF ACRYLAMIDE)
FORMATION IN COOKED)
STARCHY FOODS)
Group Art Unit: 1794)
Confirmation No.: 2884)
Customer No.: 21036)
Examiner: Viren A. Thakur)
Attorney Docket No.: Awad-George 4.1-7)

DECLARATION OF AZIZ C. AWAD UNDER 37 C.F.R. § 1.131

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

I, Aziz C. Awad, the inventor in the above application, state as follows:

[0001] I hold a Ph.D. (2000) in Food Science (Food Chemistry major) from Michigan State University. My research areas include lipid and protein chemistry with a focus on the preservation and disinfection of food products using natural antimicrobial agents. I hold several patents and have many publications. I have several professional memberships in a variety of scientific fields: Institute of Food Technologists, American Heart Association, American Oil Chemist Society, and American Chemical society. I am the head of the research team at Mandala Technologies, LLC (Farmington Hills, MI), performing chemical and biochemical research related to food processing and antimicrobial products.

[0002] I am familiar with the contents of the above-identified application. I make this declaration to provide facts (and their chronology) related to the conception and reduction to practice of the claimed subject matter in the application.

[0003] U.S. Provisional Application No. 60/424,151, the basis of the current non-provisional application, was filed on **November 6, 2002**. The provisional application described the presently claimed process in terms of its steps and variations thereof, as shown, for example, at pages 6-16 (describing process steps and variations to be evaluated to identify operable working parameters of the process) and at Figures 1-9 (outlining various process steps and illustrating suitable apparatus for execution of the process).

[0004] Preliminary testing of the process with commercially available potatoes suggested the desirability of using raw food material initially having a low sugar content. Prior to **June 20, 2003**, I identified and acquired a batch of "Wisconsin 123" potatoes for testing based on the knowledge that the particular potatoes were supposed to have a low sugar content. The "Wisconsin 123" potatoes were obtained from the Michigan Potato Industry Commission. See Application Specification, ¶ 22.

[0005] I subsequently submitted a sample of the raw "Wisconsin 123" potatoes to an independent laboratory (Covance Laboratories, Inc.; Madison, WI) for testing to determine the sugar and amino acid profile of the potatoes. On **June 20, 2003**, Covance Laboratories issued a Report of Analysis to me (attached hereto as **Exhibit A**; sample number 30602285). The report confirmed that the raw "Wisconsin 123" potatoes had a low sugar content (<0.1 wt.% fructose, glucose, sucrose, maltose, and lactose) and significant asparagine content (initially 0.411 wt.% asparagine). The report data was incorporated into the eventual non-provisional application as Table 1. See Application Specification, p. 10. Of course, the raw "Wisconsin 123" potatoes contained at least some sugars (albeit at <0.1 wt.% for fructose, glucose, sucrose, maltose, and lactose) insofar as potatoes in general contain at least residual amounts of sugar.

[0006] Prior to July 30, 2003, I began testing the claimed process with the "Wisconsin 123" potatoes. The potatoes were evaluated in the claimed process according to the experimental variations generally outlined in Examples 1-6 and summarized in Tables 2-10 in the eventual non-provisional application. See Application Specification, ¶¶ 26-¶ 33. Once the potatoes were treated according to

the claimed process (e.g., generally including fermentation and subsequent baking/frying steps), samples of the baked/fried food samples were submitted to Covance Laboratories for acrylamide analysis to determine the acrylamide reduction values reported in the application examples. At least some of the application examples were completed prior to July 30, 2003 (e.g., fermented, fried, tested for acrylamide content). Representative analytical laboratory reports are attached hereto as **Exhibit B** (report issued **June 16, 2003**; sample numbers 30602268 and 30602269) and **Exhibit C** (report issued **June 26, 2003**; sample numbers 30604432 and 30604430). In Exhibits B and C, the first sample numbers (i.e., 30602268 and 30604432) represent control samples in which potatoes were sliced, washed, and fried without an intervening fermentation. In Exhibits B and C, the second sample numbers (i.e., 30602269 and 30604430) represent samples in which potatoes were treated according to the claimed process and reported in the filed application at Example 5 (Table 9, line 1) and Example 2 (Table 3, line 4), respectively. These representative results confirmed that the claimed process was satisfactory for its intended purpose, namely the substantial reduction of acrylamide formation in the cooked food.¹ Table A below summarizes the results of Exhibits B and C

Table A – Acrylamide Reduction Data from Exhibits B and C

Sample Number	Acrylamide Concentration	Sample Source	Acrylamide Reduction
30602268	268 ppb	Control	81%
30602269	52 ppb	Example 5, Table 9, Line 1	
30604432	263 ppb	Control	70%
30604430	80 ppb	Example 2, Table 3, Line 4	

¹ "Acrylamide Reduction" in Table A computed as $[(\text{Control} - \text{Sample}) / (\text{Control})]$ ratio of detected acrylamide concentrations. For example, sample number 30602268 (268 ppb acrylamide) and sample number 30602269 (52 ppb acrylamide) yield an acrylamide reduction of $(268 \text{ ppb} - 52 \text{ ppb}) / (268 \text{ ppb}) = 0.806 \approx 81\%$ reduction.

[0007] On **September 25, 2003**, I contacted Ian McLeod (i.e., the prosecuting patent attorney of record) to arrange for the filing of the eventual non-provisional application incorporating the "Wisconsin 123" test data.


[0008] On **September 30, 2003**, attorney McLeod provided me with a draft set of claims to be filed with the non-provisional application for review. See **Exhibit D** (letter from attorney McLeod enclosing the draft claims; attached hereto).

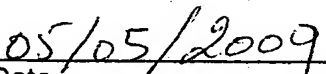
[0009] On **October 2, 2003**, attorney McLeod provided me with a draft non-provisional application for review. See **Exhibit E** (letter from attorney McLeod enclosing the draft application; attached hereto).

[0010] I approved the final non-provisional application and claims, and U.S. Application No. 10/679,714 was filed on **October 6, 2003**.

[0011] I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully Submitted,


Aziz C. Awad


Date

LIST OF EXHIBITS

- Exhibit A:** Report of Analysis from Covance Laboratories dated June 20, 2003 and providing sugar/amino acid analytical results for the "Wisconsin 123" potato variety
- Exhibit B:** Report of Analysis from Covance Laboratories dated June 16, 2003 and providing analytical results for acrylamide content of fermented, fried "Wisconsin 123" potatoes treated according to application Example 5
- Exhibit C:** Report of Analysis from Covance Laboratories dated June 26, 2003 and providing analytical results for acrylamide content of fermented, fried "Wisconsin 123" potatoes treated according to application Example 2
- Exhibit D:** Letter from attorney McLeod dated September 30, 2003 and enclosing a draft set of claims for review
- Exhibit E:** Letter from attorney McLeod dated October 2, 2003 and enclosing a draft application for review

Covance Laboratories Inc.
 3301 Kinsman Blvd.
 Madison, WI 53704
 Tel: 608/241-4471 Fax: 608/241-7227

REPORT OF ANALYSIS

COVANCE.
 THE DEVELOPMENT SERVICES COMPANY

MICHIGAN STATE UNIVERSITY
 AZIZ AWAD
 DEPT. OF FOOD SCIENCE & HUMAN NUTRITION
 LAB 312
 EAST LANSING, MI 48824

SAMPLE NUMBER: 30602285

BATCH NUMBER: 30602285

DATE ENTERED: 06/10/03

REPORT PRINTED: 06/20/03

FRESH POTATO: FRESH WI 123

ASSAY
SUGAR PROFILE

	<u>ANALYSIS</u>	<u>UNITS</u>
FRUCTOSE BY HPLC	< .1	GM/100 G
GLUCOSE BY HPLC	< .1	GM/100 G
SUCROSE BY HPLC	< .1	GM/100 G
MALTOSE BY HPLC	< .1	GM/100 G
LACTOSE BY HPLC	< .1	GM/100 G

AMINO ACIDS, FREE

	G/100 G
ASPARTIC ACID	.021
GLUTAMIC ACID	.063
PROLINE	.015
GLYCINE	.004
ALANINE	.027
CYSTINE	< .001
VALINE	.031
METHIONINE	.014
ISOLEUCINE	.012
LEUCINE	.011
TYROSINE	.024
PHENYLALANINE	.017
HISTIDINE	.023
LYSINE	.025
ARGININE	.142
ASPARAGINE	.411

Covance Laboratories Inc.
3301 Kinsman Blvd.
Madison, WI 53704
Tel: 608/241-4471 Fax: 608/241-7227



SAMPLE NUMBER: 30602285

PAGE 2

FRESH POTATO: FRESH WI 123

METHOD REFERENCES

SUGAR PROFILE

Official Methods of Analysis of AOAC INTERNATIONAL (2000) 17th Ed., AOAC INTERNATIONAL, Gaithersburg, MD, USA, Official Method 982.14. (Modified)

AMINO ACIDS, FREE

AOAC International, 982.30 'Protein Efficiency Ratio' (modified), Official Methods of Analysis, (ed.) Patricia Cunniff, Sixteenth Ed., Vol. 2, AOAC International: Arlington, VA (1995).

COVANCE LABORATORIES INC.
3301 Winsman Blvd.
Madison, WI 53704
Tel: 608/241-4471 Fax: 608/241-7227

REPORT OF ANALYSIS

COVANCE.
THE DEVELOPMENT SERVICES COMPANY

SAMPLE NUMBER: 30602368

BATCH NUMBER: 30602261

DATE ENTERED: 06/10/03

REPORT PRINTED: 06/16/03

MICHIGAN STATE UNIVERSITY
AZIE AWAD
DEPT. OF FOOD SCIENCE & HUMAN NUTRITION
LAB 312
EAST LANSING, MI 48824

POTATO CHIPS: 10

ASSAY
ACRYLAMIDES BY LCMS

<u>ANALYSIS</u>	<u>UNITS</u>
268.	PPB

METHOD REFERENCES

ACRYLAMIDES BY LCMS
United States Food and Drug Administration, Center for Food Safety and Applied
Nutrition Office of Plant & Dairy Foods and Beverages, "Detection and
Quantitation of Acrylamide in Foods". (2002)

Covance Laboratories Inc.
3301 Kinsman Blvd.
Madison, WI 53704
Tel: 608/241-4471 Fax: 608/241-7227

REPORT OF ANALYSIS

COVANCE.
THE DEVELOPMENT SERVICES COMPANY

SAMPLE NUMBER: 30602269

BATCH NUMBER: 30602261

DATE ENTERED: 06/10/03

REPORT PRINTED: 06/16/03

MICHIGAN STATE UNIVERSITY
AZIZ AMAD
DEPT. OF FOOD SCIENCE & HUMAN NUTRITION
LAB 312
EAST LANSING, MI 48824

POTATO CHIPS: 19

ASSAY
ACRYLAMIDES BY LCMS

<u>ANALYSIS</u>	<u>UNITS</u>
52.	PPD

METHOD REFERENCES

ACRYLAMIDES BY LCMS

United States Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Plant & Dairy Foods and Beverages, "Detection and Quantitation of Acrylamide in Foods". (2002)

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Madison, WI 53704
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REPORT OF ANALYSIS

COVANCE.
THE DEVELOPMENT SERVICES COMPANY

MICHIGAN STATE UNIVERSITY
AZIZ AWAD
DEPT. OF FOOD SCIENCE & HUMAN NUTRITION
LAB 312
EAST LANSING, MI 48024

SAMPLE NUMBER: 30604432

BATCH NUMBER: 30604427

DATE ENTERED: 06/17/03

REPORT PRINTED: 06/26/03

POTATO CHIPS: 29

ASSAY
ACRYLAMIDES BY LCMS

<u>ANALYSIS</u>	<u>UNITS</u>
263.	PPB

METHOD REFERENCES

ACRYLAMIDES BY LCMS

United States Food and Drug Administration, Center for Food Safety and Applied
Nutrition Office of Plant & Dairy Foods and Beverages, "Detection and
Quantitation of Acrylamide in Foods". (2002)

Covance Laboratories Inc.
3301 Kinsman Blvd.
Madison, WI 53704
Tel: 608/241-4471 Fax: 608/241-7227

REPORT OF ANALYSIS

COVANCE.
THE DEVELOPMENT SERVICES COMPANY

SAMPLE NUMBER: 30604430

BATCH NUMBER: 30604427

DATE ENTERED: 06/17/03

REPORT PRINTED: 06/26/03

MICHIGAN STATE UNIVERSITY
AZIZ AMAD
DEPT. OF FOOD SCIENCE & HUMAN NUTRITION
LAB 312
EAST LANSING, MI 48824

POTATO CHIPS: 27

ASSAY
ACRYLAMIDES BY LCMS

<u>ANALYSIS</u>	<u>UNITS</u>
80.	PPB

METHOD REFERENCES

ACRYLAMIDES BY LCMS
United States Food and Drug Administration, Center for Food Safety and Applied
Nutrition Office of Plant & Dairy Foods and Beverages, "Detection and
Quantitation of Acrylamide in Foods". (2002)

MCLEOD & MOYNE, P.C.
ATTORNEYS AND COUNSELORS AT LAW
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2003 September 30

Dr. Aziz Awad

Re: Healthtreat 4.1-1
Title: Reduction of Acrylamide
Formation in Cooked Starchy Foods
Inventor: Aziz Awad

By Hand
9/30/03

Dear Aziz

Enclosed is a draft of claims for the above referenced application for you to review. You then need to telephone me to discuss them.

If there are any questions, please let me know.

Best wishes.

Sincerely,



Ian C. McLeod
ICM/jrh
Encl.

McLEOD & MOYNE, P.C.
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2003 October 2

Dr. Aziz Awad
3003-2A Trappers Cove Trail
Lansing, Michigan 48910

Re: Healthtreat 4.1-1
Title: Reduction of Acrylamide
Formation in Cooked Starchy
Foods
Inventor: Aziz Awad

Dear Aziz:

Enclosed is a draft of the above referenced application for
your review. We can then discuss it.

Best wishes.

Sincerely,

Ian C. McLeod
ICM/ejm
encl.

cc: Mr. Michael George, Jr.
HEALTHTREAT, INC.
30777 Northwestern Highway - Suite 300
Farmington Hills, Michigan 48334